

Swiss Institute for Translational  
and Entrepreneurial Medicine

siteminsel

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**UNIVERSITY  
OF BERN**

CAS · DAS · MAS

# Regulatory Affairs and Quality Management



**WEITER  
BILDUNG  
UNIBE**

# Academic Degree Program for Regulatory Affairs and Quality Management Specialists

Regulatory specialists are integral to bringing novel medical devices to market. They require a breadth of managerial and interpersonal skills in addition to technical, clinical and legal knowledge. This program offers career specialized training in Regulatory Affairs, Quality Management and Advanced Regulatory Affairs with particular focus on the European Medical Device Regulations.

## Education tailored to your own needs

The program is conceptualized as an part-time program that can be reconciled with your professional work. The modular structure allows you to pursue your goals tailored to your own needs. You can start with a Certificate of Advanced Studies (CAS) and gradually build it up to a Master of Advanced Studies (MAS) in Regulatory Affairs and Quality Management degree over time.

## Study format

Each CAS corresponds to at least 15 ECTS credits, and includes around 1-2 in-person event per month, completed by individual work. The modules are taught in a blended learning environment and utilize e-learning, peer learning and interactive discussions with experts, on site lectures, workshops, and case studies. Small class sizes allow for large flexibility while at the same time permitting to profit from the lecturers' expertise.

## Academic degree

Our education programs are offered under the umbrella of the Medical Faculty of the University of Bern. Upon successful completion of the program, the University of Bern awards a Master / Diploma / Certificate of Advanced Studies.

## Certificate of Advanced Studies (CAS) in Regulatory Affairs

- Introduction to Regulatory Affairs
- Pre-submission Regulatory Affairs
- Post-submission Regulatory Affairs

## Certificate of Advanced Studies (CAS) in Quality Management in Translational Medicine

- Introduction to Quality Management
- Design control: from input to validation
- Risk management & usability engineering

## Certificate of Advanced Studies (CAS) in Advanced Regulatory Affairs

- ATMP Regulatory Affairs
- Combination Products
- FDA & Foreign Regulatory Affairs
- Medical Device Clinical Evaluation
- AI & Digital Health Technologies

## Why study with us?

- Increase your career prospects
- Obtain an internationally recognised degree from a prestigious Swiss university
- Gain expert insights from academia and industry
- Connect and exchange with peers and lecturers
- Acquire extensive knowledge and skills development in relevant topics
- Keep up with the latest regulatory changes and implementations
- Pursue a «Master of Advanced Studies» title in a stepwise approach
- Profit from small class sizes and flexibility of study formats

## Industry meets academia

Our experts from academia, industry and regulatory authorities, carry the teaching responsibility and support us in educating healthcare and regulatory specialists. They combine deep theoretical knowledge from their innovative research, with the latest practical insights from their extensive work with industry.

## Who is the program for?

Graduates interested in commencing a career as a regulatory affairs specialist or quality manager within a medical device environment and mid-level experienced professionals who would like to raise their proficiency to the next level. The program also targets those from complementary disciplines such as entrepreneurship, research and development, and management, seeking comprehensive and practical knowledge in this field.

## Duration

CAS	2 Semester (< 1 year)
DAS	3 Semester (1.5 years)
MAS	4 Semester (2 years)

## Language

English

## Location

Bern, Switzerland  
(hybrid participation possible)

## Study fees

CAS	CHF 12'600
DAS	CHF 23'100
MAS	CHF 31'500

## Application deadlines

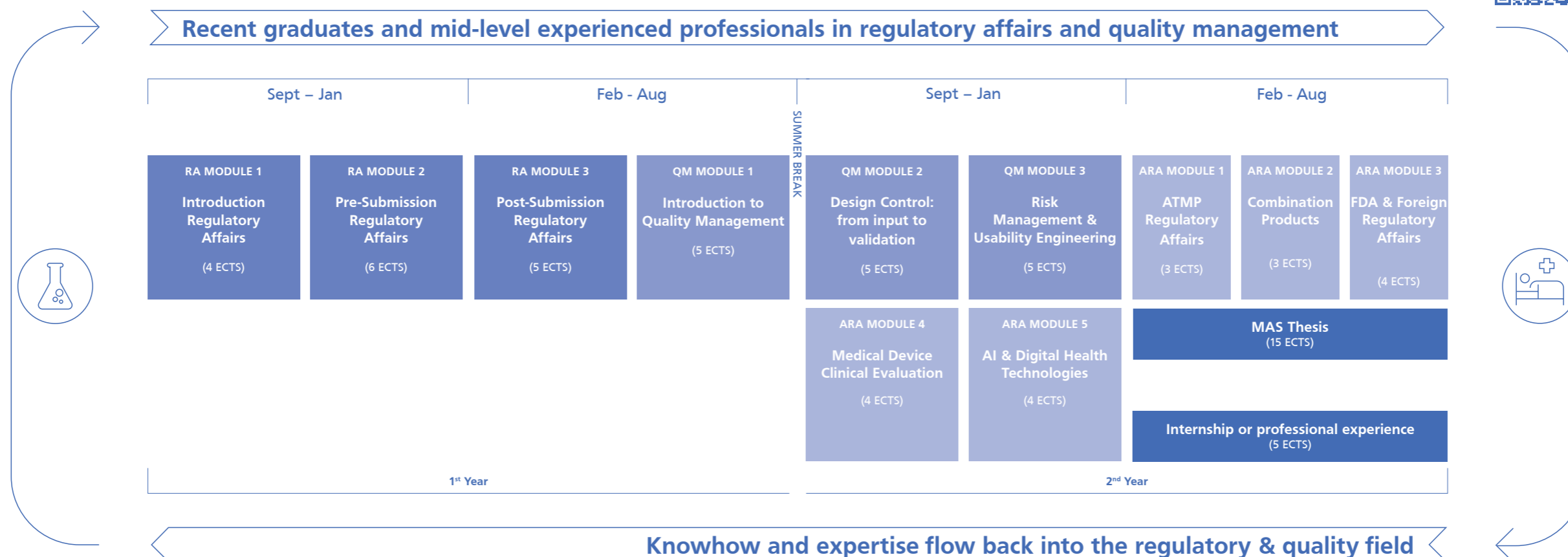
Spring term	December 15
Fall term	July 15

## Contact

[school.sitem@unibe.ch](mailto:school.sitem@unibe.ch)

## Registration

[Registration & more information](#)





April 2026

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